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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/420,719	10/20/1999	MARIKO MIYASHITA	10059-308(P2	3194

570 7590 07/28/2004

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2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103-7013

EXAMINER	
PADMANABHAN, KARTIC	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/420,719	MIYASHITA ET AL.	
	Examiner	Art Unit	
	Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,24,25,29 and 30* is/are pending in the application.

4a) Of the above claim(s) *30* is/are withdrawn from consideration.

5)☒ Claim(s) *29* is/are allowed.

6)☒ Claim(s) *19,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *19,24,25,29 and 30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 October 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/9/04 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 19, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obata et al. (US Pat. 5,571,419) in view of Short et al. (US Pat. 6,183,740 B1) or Lihme et al. (US Pat. 5,935,442).

Obata et al. teach a method and apparatus for producing pure water. According to the reference, raw water is introduced into filtration units through a pipe and treated. After undergoing cation exchange, the water is supplied to an acidic softened water tank and stored. It is inherent that the pH of the raw water is altered in some way in this tank. An oxidizing agent, which may be hydrogen peroxide, is added to the raw water through a pipe. A heater provided with a boiler then heats the water. The water is then introduced into a reaction chamber where urea is decomposed by catalytic heat treatment. At the end of the process, the now pure water is released (col. 4, lines 30-67 and Figs. 1-8). Since well water and tap water can be filtered using the apparatus of the reference, it is inherent that the purified water is fit for human consumption in some fashion, and a person tasting water is interpreted as a biosensor analyzing a sample. However, the reference does not teach the use of enzymes as the catalyst.

Short et al. teach the use of phytases in water treatment. The reference teaches that biological enzymes are effective in the bioconversion of potentially noxious substances into useful bioproducts.

Lihme et al. teach water treatment, wherein the active substance may be an enzyme, catalyst, or other treatment material.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use enzymes for water treatment as in Short et al. or Lihme et al. with the treatment method of Obata et al. because both Short et al. and Lihme et al. teach that enzymes are useful in water treatment methods. In addition, Lihme et al. contemplate the use of various agents for water treatment, including catalysts and enzymes, which would give one of skill in the art a reasonable expectation of success in using any number of agents, such as enzymes, to convert noxious substances into harmless ones, depending on the makeup of the water being treated.

6. Claims 19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasuda et al. (US Pat. 5,378,635). Yasuda et al. teach a method of measuring catecholamine. The reference discloses sample pretreatment means and sample dispensing means in the form of a syringe, which is couple to the pretreatment means. A syringe inherently has sample introduction and sample releasing parts. Maleimide, mixed with a buffer solution to adjust the pH to around 7.3, is added to the sample dispensing means or the sample pretreatment means and reacts with SH compounds, which inhibits the interference of fluorescence inducing reaction. However, the reference does not teach that the sample pretreatment means is physically independent of the biosensor.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make the pretreatment means separable from the biosensing means, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. In addition, in this case, it is noted that although the syringe may be connected to the biosensing means via tubing, the syringe

can be made separable from the biosensor by simply removing it from the tubing. As such, after the sample is pretreated in the syringe, the syringe can then be attached to the tubing to convey the treated sample to the biosensor.

7. Claims 19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (US Pat. 5,262,305), Foulds et al. (US Pat. 5,124,253), or Nankai et al. (US Pat. 4,431,507).

Heller et al. teach a biosensor including an interferant eliminating catalyst. The apparatus of the invention has an interferant eliminating layer, including a catalyst, wherein the catalyst is capable of oxidizing and thereby eliminating a plurality of interfering compounds from the sample before it reaches the sensor (col. 1). The catalyst mediates oxidation of an interferant in the presence of an oxidant to yield a non-interfering compound that does not interfere with the biosensor's function. In addition, the catalyst may be a natural enzyme (col. 4). Furthermore, the apparatus of the reference inherently includes a sample introducing part and sample releasing part, as these parts are interpreted as any part of the apparatus that allows the entry and release of a sample. These parts are also located on either sides of the control means, as a sample enters the top of the layer, travels through the layer, where interferants are removed, and then is released to the sensing layer from the bottom of the interferant removing layer (figures 2 and 3).

Foulds et al. teach a device and method, wherein isozymes are employed to remove or inactivate endogenous alkaline phosphotase, thereby minimizing interference. In addition, the system also comprises a suitable buffer to alter the pH of the sample solution, often blood with a pH of 7.4, to an alkaline value suited to the enzyme of the test element (col. 4). The apparatus of the reference inherently includes a sample introducing part and sample releasing part, as these parts are interpreted as any part of the apparatus that allows the entry and release of a sample.

These parts are located on either sides of the control means, as a sample enters one side of the layer, travels through the layer, where interferants are removed, and then is released on the other side.

Nankai et al. teach a device in which an electrode is provided to electrochemically oxidize interfering materials in the sample solution. The enzyme of the electrode oxidizes interfering materials such as uric or ascorbic acid (col. 3). The apparatus of the reference inherently includes a sample introducing part and sample releasing part, as these parts are interpreted as any part of the apparatus that allows the entry and release of a sample. However, none of the references teach sample pretreatment means that is physically independent of the biosensor.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make the pretreatment means separable from the biosensing means of the references, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Allowable Subject Matter

8. In view of applicant's amendments, claim 29 is allowable over the prior art of record.

9. The following is a statement of reasons for the indication of allowable subject matter: the closest prior art of record fail to disclose or teach a sample solution treatment instrument comprising a sample treating unit and a sample supply unit, wherein the sample treating unit contains an agent that converts a sample solution to a condition for analysis with a biosensor that electrochemically measures a specific component in the sample solution, the agent selected from the group consisting of a catalyst that converts an interfering substance in the sample solution to

a harmless substance having no adverse effect on a measurement result of the specific component obtained by analysis with the biosensor, an adsorbent that adsorbs and removes an interfering substance from the sample solution, and a buffer agent that adjusts a pH of the sample solution to a pH range adequate for an activity of an enzyme in the biosensor, and the sample supply unit is made of an elastic material that retains the sample solution inside the sample supply unit, wherein the sample supply unit is located adjacent to the sample treating unit such that the sample solution passes through the sample treating unit to the sample supply unit after treatment, but wherein the instrument is not physically coupled to a biosensor.

Response to Arguments

10. Applicant's arguments filed 6/9/04 have been fully considered but they are not persuasive.

11. Applicant argues that Obata does not disclose consumption of water by humans, which is interpreted as the biosensor, such that contamination with urea would not be an interferant. This is not convincing because the disclosure that the purified (free of urea as an interferant) water is used for well and city water renders human consumption inherent. In addition, both Short and Lihme at minimum generally disclose the use and effectiveness of enzymes in wastewater treatment. For example, Lihme teaches that an enzyme may be the active material used to purify water (Col. 12, lines 16-24). In addition, while the examiner acquiesces that Obata does not teach enzymes for interferant removal, the secondary references cure this deficiency, for reasons discussed under 35 USC 103; therefore, using the teachings of Short or Lihme regarding the use of enzymes in water treatment, one would have had the motivation to modify the teaching of Obata to use enzymes for water treatment with a reasonable expectation of success.

12. Applicant's argument that the references do not teach analysis by a biosensor that electrochemically measures a specific component is moot because such a limitation is merely the intended use of the sample after treatment. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

13. Applicant argues that the Yasuda reference teaches that the sample already has buffer before it is inserted into the control means (syringe); however, while this may be the case, the buffer still exerts its effect while in the syringe, such that the limitation of a control means that may be buffer is met. In addition, applicant's arguments that it is inefficient to separate the syringe from the fluorometer are unconvincing. One of skill in the art at the time of the invention would have recognized that a syringe is easily removable from the biosensor of the reference, and would have numerous reasons for actually removing the syringe from the tubing attaching it to the biosensor, such as replacement or cleaning. Further, the courts have held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

14. Applicant also argues that there is no motivation in Heller, Foulds, or Nankai to separate the control means from the biosensor means; however, courts have held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v.*

Erlichman, 168 USPQ 177, 179. There is no requirement that the combination be more efficient or better in any way.

Conclusion

Claims 19, 24, and 25 are rejected, and claim 29 is allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*** KP

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07/23/04